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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|---------------------------------|---------------------|--------------------------------|
| 10/544,112 | 08/02/2005 | Takanori Miyoshi | Q88453 | 9429 |
| 23373 | 7590 | 04/26/2010 | | |
| SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037 | | | | EXAMINER CHRISS, JENNIFER A |
| | | ART UNIT 1786 | | PAPER NUMBER ELECTRONIC |
| | | NOTIFICATION DATE 04/26/2010 | | DELIVERY MODE ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | |
|------------------------------|--------------------------------------|---------------------------------------|
| Office Action Summary | Application No. 10/544,112 | Applicant(s) MIYOSHI ET AL. |
| | Examiner JENNIFER A. CRISS | Art Unit 1786 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 03 March 2010.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-4,6-8 and 10-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4,6-8 and 10 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/GS-68)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Response to Remarks

1. The Applicant's Remarks, filed March 3, 2010, have been entered and have been carefully considered. No claims are amended, claims 11 - 13 remain withdrawn and claims 1 – 4, 6 – 8 and 10 – 13 are pending. The invention as currently claimed is not found to be patentable for reasons herein below.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

3. Claims 1 – 4, 6 – 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Technical Paper entitled Technique Paper for Wet-Spinning Poly(L-lactic acid) and Poly(DL-lactic-co-glycolide) Monofilament Fibers".

The paper discusses wet-spinning fibers made of polylactic acid or PLGA which was dissolved in varying concentrations of solvent systems including chloroform or methyl chloride. The paper indicates that the coagulation bath included materials such as PEG 200 as well (Materials and Methods). The paper teaches that fiber mechanical and physical properties such as strength, diameter, surface tension and so on are strongly dependent on the choice of coagulation bath (Materials and Methods). The fiber diameters of 30 microns or less was easy to achieve according to the paper by choosing the appropriate spinning conditions, solvents, polymer concentrations and

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draw ratios (Discussion). The paper indicates in the results that they have produced fibers with diameters as small as 28 microns (Results). Additionally, the paper indicates that the fibers can be used as scaffoldings for numerous cell attachment and growth situations and indicates that the cells formed web structures between adjacent fibers (In vitro and in vivo biological results); the Examiner equates this to Applicant's "a fiber structure comprising porous fibers".

Although the paper does not specifically indicate using polylactic acid, chloroform and PEG 200 together to create a fiber, as demonstrated by the paper, all of the component parts are known and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use create a fiber using a combination of polylactic acid, chloroform and PEG 200, since the combination of elements would have yielded the predictable result of a tailored fiber based on the desired mechanical and physical properties such as strength, diameter and surface tension for the particular end use.

The paper discloses the claimed invention except for that the average fiber diameter is 0.1 to 20 microns. It should be noted that the fiber diameter is a result effective variable. As discussed above, the fiber diameter can be controlled by using the appropriate spinning conditions, solvents, polymer concentrations, coagulation bath and draw ratios. It would have been obvious to one having ordinary skill in the art at the time the invention was made to create the fiber with a diameter of 0.1 to 20 microns since it has been held that discovering an optimum value of a result effective variable involves

only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In the present invention, one would have been motivated to optimize the diameter of the fiber to 0.1 to 20 microns in order to create a fiber tailored to the particular cell attachment requirements.

The paper teaches the claimed invention above but fails to teach that the fiber porosity is at least 5%. It is reasonable to presume that the porosity of at least 5% is inherent to the fiber of the paper. Support for said presumption is found in the use of like materials (i.e. a fiber made from a combination of PLA, PEG 200 and chloroform with a small diameter) which would result in the claimed property. The burden is upon the Applicant to prove otherwise. *In re Fitzgerald* 205 USPQ 594. In addition, the presently claimed properties would obviously have been present once the product of the paper is provided. Note *In re Best*, 195 USPQ at 433, footnote 4 (CCPA 1977). Reliance upon inherency is not improper even though the rejection is based on Section 103 instead of 102. *In re Skoner*, et al. (CCPA) 186 USPQ 80.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Response to Arguments

4. Applicant's arguments filed March 3, 2010 have been fully considered but they are not persuasive.

5. Applicant argues that the Technical Paper entitled "Technique Paper for Wet-Spinning Poly(L-lactic acid) and Poly(DL-lactic-co-glycolide) Monofilament Fibers" is not prior art as the publisher's website indicates that the reference was actually published on July 9, 2004. The Applicant provides a copy of the publisher's website to show the asserted July 9, 2004 publication date. The Examiner contacted the publisher of the article via the website discussed by Applicant. According to Mary Ann Liebert, Inc. Proofs/Reprints department, *the December 2003 issue of Tissue Engineering was officially published in November 2003. We are looking into why the July 2004 date is listed on the website as this is incorrect. Thank you for bringing this error to our attention.* The Examiner has provided a copy of this email correspondence with this Office Action. As such, the publication date of November 2003 is before the February 12, 2004 US filing date of the instant application. Applicant has not argued the merits of the rejection, therefore, the rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER A. CRISS whose telephone number is (571)272-7783. The examiner can normally be reached on Monday - Friday, 8:30 a.m. - 6 p.m., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Tarazano can be reached on 571-272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. A. C./
Primary Examiner, Art Unit 1786

/Jennifer A Chriss/
Primary Examiner, Art Unit 1786

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